REMARKS/ARGUMENTS

35 U.S.C. § 112

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In making this rejection, the Examiner notes that the claim recites a "polymer film coating at least 80% of the core." The Examiner states that the 80% requires an explanation. Applicants respectfully disagrees that the term 80%" is indefinite. In paragraph 57 of the present application it states that the polymer coating preferably coats at least 70% of the oxazolidinone in the core, more preferably at least 80% of the oxazolidinone in the core, and even more preferably at least 90% of the oxazolidinone in the core. The specification further states that in a preferred embodiment the particles are "microencapsulated oxazolidinone particles." The person skilled in the art readily appreciates that microencapsulated particles are particles in which the interior particles are surrounded or enveloped by another substance. Quite clearly the term "80%" in claim 4 refers to the percentage of the surface of the interior particle which is covered. Reconsideration of and withdrawal of this rejection is respectfully requested.

Nonstatutory Double Patenting Rejection

U.S. 10/763,299 relates to a composition which includes at least two doses of a coated drug particle and a viscosity enhancing agent. There is nothing in U.S. Application 10/763,299 which teaches or suggests the synergistic effect of sorbitol and another sugar in suppressing the solubility of the drug substance in the coated particle. Reconsideration of and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 102 (Percel et al., U.S. 6,451,345)

Claims 1-3, 5-9, 16, 20-22, 27-29, 31-35, 41-42, and 46 are rejected under 35 U.S.C. § 102(a,e) as allegedly being anticipated by Percel et al., U.S. 6,451,345. Applicants respectfully disagrees. Percel et al. mention sweeteners (column 4, line 16) and disintegrants which could include certain sugars (column 4, line 23). Applicants' invention relates to coated oxazolidinone particles contained in a formulation which includes "a mixture of sugars, comprising sorbitol and at least one other sugar." Unexpectedly Applicants have found that this mixture of sugars suppresses the solubility of the oxazolidinone, thereby enhancing the taste masking provided by the coated particles. The mixture of sugars including sorbitol is not disclosed in Percel, and accordingly it is respectfully submitted that

Percel et al. does not anticipate Applicants' invention. Reconsideration of and withdrawal of this rejection is respectfully solicited.

35 U.S.C. § 103(a) (Percel et al. (U.S. Patent 6,451,345) in view of Sparks et al. (U.S. Patent 6,534,556) and further in view of Tam et al. (U.S. Patent 6,495,154)

Claims 1-46 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Percel et al. in view of Sparks et al. and further in view of Tam et al. Applicants respectfully disagree. The invention of Tam et al. relates to "the treatment of premature ejaculation, preferably by on demand administration of clomipramine (technical field)." The term "on demand" refers to the administration of an active agent immediately prior to sexual activity (column 4, lines 41-43). Tam et al. lists conventional nontoxic solid carriers which include "mannitol, lactose, starch, magnesium stearate, sodium saccharin, talc, cellulose, glucose, sucrose, magnesium carbonate, and the like (column 6, lines 43-45)." Tam et al. also list glucose, sucrose, fructose, sorbitol, anise oil, cinnamon oil, cocoa, menthol, orange oil, and vanillin as taste masking agents. Clearly, because of the emphasis on "on demand" administration, Tam et al. is referring to compositions which release their drug component quickly so that it is effective in achieving the desired result. The sugars disclosed in Tam et al. as carriers and taste masking agents would not have the effect of suppressing the solubility of the active drug ingredient, because this would not be consistent with on demand dosing. Accordingly, Tam et al. does not disclose the suppression of solubility by the combination of sorbitol and another sugar. Quite clearly, the combination of Tam et al. and Percel et al. do not disclose a key feature of Applicants' invention.

Sparks et al. relate to a powder in which the active ingredient and optionally an excipient are contained in a micromatrix where the active ingredient and the excipient, if present, are uniformly distributed throughout the polymer (column 2, line 64, to column 3, line 5). The powder can be dispersed or suspended in a liquid vehicle (column 3, lines 21-22). Although syrups may be used as a suspending agent in the invention of Sparks et al., the taste masking of unpleasant ingredients is provided by the polymer coat (column 8, lines 21-26). Accordingly, Sparks et al. do not provide a teaching of the effect of a mixture of sorbitol and another sugar in suppressing the solubility of a drug. It is respectfully submitted that the combination of Sparks et al., Tam et al. and Percel et al. does not provide for a teaching of the beneficial effect achieved by the combination of sorbitol and another sugar. Accordingly, these three references alone or together do not disclose Applicants' invention. Reconsideration of and withdrawal of this rejection is respectfully solicited.

Prompt and favorable consideration of this application is respectfully requested. If the Examiner believes that personal communications will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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